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## Clinical Chemistry: A Professional Field for Physicians and Natural Scientists in Europe<sup>1)</sup>

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**Summary:** A detailed analysis of the profession of clinical chemistry reveals the following facts.

1. Clinical chemistry is definitely an interdisciplinary subject between natural science and medicine. The major part of clinical chemistry is natural science and therefore theoretical science. To a lesser extent, however, clinical chemistry is practical science or "action science" which is aimed at a certain action.
2. The question "*Is clinical chemistry a professional field for physicians, for scientists or for both?*" can be answered with the statement: It follows from its historical development and its characteristic theory and practice, and is de facto true throughout the world, that clinical chemistry is a professional field for physicians and natural scientists.
3. The broad scope of the technical field and the challenges to be expected in future within the framework of the European Community will require the recruiting aspiring clinical chemists both from medicine and from the natural sciences.
4. Qualified postgraduate training is more important than the nature of the initial study course.
5. Apart from providing special knowledge and particular abilities, postgraduate training must make the younger generation familiar with the ways of thought of the physician and of the natural scientist.
6. Successful work as a clinical chemist requires "extra-functional" qualifications, such as the ability to conduct dialogue and teamwork with the clinician.
7. The national differences which exist in the definition of the professional pattern "clinical chemist" are a hindrance to the future development of the discipline in the European Community. The starting point for recognition of the profession must be an agreed definition among the professionals of the countries of the European Community of the professional field of the clinical chemist.

"If I am not both a chemist and a physician, then I am nothing; but the difficulty of my existence is in that combination"

J. W. L. Thudichum (1869) (1)

### Introduction

The European market and the unification of the Federal Republic of Germany with the German Democratic Republic will make it necessary to adapt and harmonize in many areas. This also applies to the professional fields of the scientific disciplines which

have considerable national differences. Such differences are found to a particular degree in the professional area of clinical chemistry. In some of the countries, clinical chemistry is definitely a medical subject whereas in other countries the natural science content of the discipline is emphasized. Adaptations will be

<sup>1)</sup> Based on a lecture at the Conference "Clinical chemistry and the European internal market 1992", Bonn, 5.–7. 7. 1990, of the Deutsche Gesellschaft für Klinische Chemie

Before answering the question, various aspects of the subject of clinical chemistry will be considered with the aim of deriving from them arguments for a rational solution of the problem. It should be pointed out that the term "clinical chemist" in the following observations always includes both sexes.

Clinical chemistry has been a separate professional field since about 1840, i. e. for about 150 years. Detailed studies of the historical development of clinical chemistry, which have been published in recent years (2, 3), show that its roots lie in chemistry, *materia medica*, pathology and clinical medicine (fig. 1). The new subject originated with the start of "scientific"

## The Professional Field of Modern Clinical Chemistry (5-8)

To define the professional field of present-day clinical chemistry, a brief answer will first be given to the questions: "What is clinical chemistry?", "How does clinical chemistry operate?", "Where does clinical chemistry take place?". Finally, the question "What professional qualifications are necessary for the clinical chemist?" will be discussed, being of special interest in the present context. From these various facets, the "professional field qualification" or the "personnel profile" of the clinical chemist can then be derived.

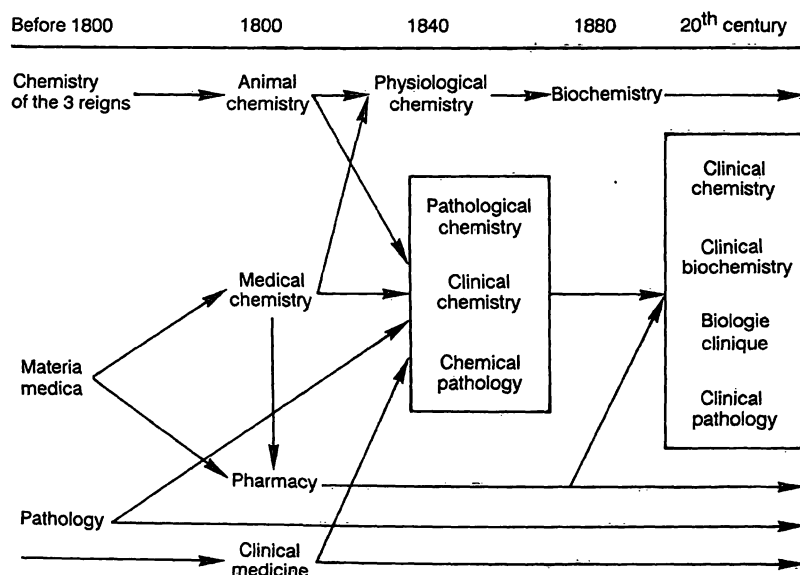


Fig. 1. Development of clinical chemistry as a discipline in the 19th century.

In our time, various *definitions* have been proposed for "clinical chemistry" and we shall pick out one here which has to some extent assumed an official character. It is the proposal made by *Manuel C. Sanz & Per Lous* for the International Federation of Clinical Chemistry (IFCC) (9):

*"Clinical chemistry encompasses the study of the chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment and prevention of disease"*.

The first part of this definition indicates the interdisciplinary nature of the subject and can only be interpreted in the sense that the "study of the chemical aspects of life in health and illness" must be carried out jointly with clinical medicine.

It follows from the definition that the subject clinical chemistry itself covers various *areas* which are summarized in table 1. The first area covers the important task of clinical chemistry in health care. For this, *Poul Astrup* coined the term "centralized analytical activity" (10) which points to the centralized hospital laboratory (11). Research in clinical chemistry includes subject-oriented parts, such as methodology and the development of new clinical chemical tests; on the other hand, research on biochemical aspects of disease is part of basic medical research. It cannot be the domain of clinical chemistry alone and should be a substantial part of basic research in many clinical disciplines (12).

Tab. 1. Areas of clinical chemistry

*"Centralized analytical activity"*

- Investigations of patient material with analytical chemical methods for diagnosis, therapy control and prevention of disease.
- Organization, management and operational control of centralized laboratories.

*Research*

- "Study of the method": Analytics
- "Study of the phenomena": related to the clinical use of quantities ("functional aspects"). Theory of clinical chemical tests.
- Research on biochemical aspects of diseases (pathobiochemistry (as part of basic medical research)).

*Teaching, including further training and postgraduate study*

It is not possible to deal in detail here with *methodology*. This applies in particular to that area of research, where new techniques are applied. Basically, clinical chemistry will always be analytical chemistry with the aim of carrying out qualitative or quantitative

determinations of substances in biological materials. The extreme complexity of biological materials, whether body fluids, cells, tissues or other materials, requires the use of numerous analytical techniques which are based on chemical, physical, molecular biological, immunological or biological principles. Thus, in addition to the classical methods of chemical and biochemical analysis, and depending on the analytical problem in question, automated analyses involving complicated instruments are being increasingly used. In view of the complexity of the analysed material, high-resolution separation methods, such as HPLC are indispensable. Inadequate analytical specificity and sensitivity of many classical methods of analytical chemistry has led to the use of enzymatic and immunochemical methods. Finally, DNA analysis offers new possibilities and new horizons.

The procedural protocol of clinical chemistry differs according to the objective. The "centralized analytical activity" includes all steps shown in abbreviated form in table 2. In research, the initial emphasis lay in the investigation of body fluids to find disease indicators. Today the aims have changed, and the pathogenesis of disease is now investigated with cytobiologically oriented methods, utilizing the findings of modern molecular biology.

Tab. 2. Correct clinical chemical investigation

*Preanalytical phase*

- choice of the quantity to be measured
- preparation of the patient for the examination
- obtaining patient material for the examination

*Analytical phase*

- choice of the method
- carrying out the analysis

*Post-analytical phase*

- analytical evaluation of the result
- medical evaluation of the result

*Interpretation, consultation with the clinician*

As a consequence of these activities clinical chemistry is conducted not only in laboratories of primary health care; it can also be an essential activity of research institutions and industrial laboratories (tab. 3).

Tab. 3. Where does clinical chemistry take place?

- University institutes, teaching hospitals
- Hospitals
- Laboratories of out-patient care
- Research institutes
- Industrial laboratories
  - diagnostica and diagnostics equipment manufacturers
  - pharmaceutical industry
  - research & development, application laboratories

## Clinical Chemistry from the Viewpoint of Theory of Science

From the outset, clinical chemistry was an interdisciplinary subject between medicine and natural sciences. What is the difference between medicine and natural sciences? This question requires a short excursion into the theory of science. In a remarkable book (13), the American medicine theoretician *Alvan R. Feinstein* wrote about "two cultures", "art" and "science", which, in medicine, exist alongside each other. According to this author, "art" in medicine denotes the skilled practicing of the clinician and "science" the scientific research of the clinician. The idea of the "two cultures" goes back to the English writer and physicist *Charles Percy Snow*, who described the gap between the areas of the natural sciences and the liberal arts or humanities (14). *Feinstein* (13) sees a similar contrast between "art" and "science" in medicine.

This contrast is also discussed in the modern theory of science (15). Thus, a distinction is made between "theoretical sciences" and "practical sciences". Theoretical sciences are aimed at obtaining knowledge, whereas practical sciences are aimed at performing actions. The natural sciences are for example described as theoretical sciences. They explain very clearly the nature of thought in theoretical sciences: The "*natural scientific method*" consists in setting up theories on the basis of data obtained by observation and experiment. Frequently, the theories postulated serve to clarify causal relationships. In contrast, clinical medicine is described as a practical science or "action science" which is aimed at a certain action (16). As a practical science, clinical medicine certainly utilizes the results of theoretical sciences, including medical disciplines. The essential differences of theoretical and practical sciences are summarized in table 4.

Tab. 4. Theoretical and practical science

	Theoretical science	Practical science
	"science"	"art"
<i>Objectives</i>	knowledge generally valid statements	actions singular statements
<i>Modes of operation</i>	investigations, experiments, postulation of theories	decisions at present on the basis of data from theoretical sciences
<i>Requires in particular</i>	intelligence, reasoning	judgement, experience
<i>Typical</i>	radicalness in questioning and method	search for reasonable compromise
<i>Examples</i>	way of thought of the scientist	way of thought of the physician

How does clinical chemistry fit into this scheme? There is not doubt that the major part of clinical chemistry is natural science, i.e. theoretical science, since its analytical methods and pathobiochemistry belong to this category. To a lesser extent, however, clinical chemistry is practical science. This is at least partly true in the assessment and interpretation of laboratory findings. These are always singular statements related to a unique patient, even when they are based on the theories and results of theoretical science. Accordingly actions should follow from the findings. This is clearly shown by examples such as coagulation tests or therapeutic drug monitoring. In both cases, the laboratory finding determines the subsequent therapy for a specific patient. In conclusion, clinical chemistry is not only a theoretical science, since it also contains a small but not insignificant proportion of practical science. In contrast, basic medical disciplines like anatomy, physiology, biochemistry as well as pathobiochemistry, seem to be exclusively theoretical sciences in the sense of our definitions. It is this peculiarity which gives clinical chemistry its bridging function between natural sciences and clinical medicine.

## The Profession of the Clinical Chemist

In the above remarks clinical chemistry has been considered mainly as scientific discipline. However, in the present discussion, it is just as important to consider clinical chemistry as a profession. In the sociological theory of professions a distinction is made between the positions of the professions in accordance with the degree of their professionalization. A profession is distinguished by an obligation to the society and by a systematized and specialized knowledge. A classical description of the profession was given by *Carr-Saunders & Wilson* (17):

*"The practitioners [of a profession], by virtue of prolonged and specialized intellectual training, have acquired a technique which enables them to render a specialized service to the community. This service they perform for a fixed remuneration whether by way of fee or salary. They develop a sense of responsibility for the technique which they manifest in their concern for the competence and honour of the practitioners as a whole — a concern which is sometimes shared with the state. They build up associations, upon which they erect, with or without the co-operation of the state, observance of certain standards of conduct. Material considerations of income and status are not neglected, but the distinguishing and overruling characteristic is the possession of a technique. It is the existence of specialized intellectual techniques, acquired as the result of pro-*

*longed training, which gives rise to professionalism and accounts for its peculiar features".*

In table 5 criteria indicative of a profession are summarized (18, 19). Nearly all these criteria are fulfilled for the profession of the clinical chemist. To this extent, this profession does not differ in nature from that of a physician or a lawyer. The question of interest for our subject is how the professions develop, and how the professional requirements for their members, i. e. the "professionals", are established. This can be done within scientific societies or professional organizations, but also by legal definition by the legislator. In this connection, the sociologist *Hansjürgen Daheim* remarks (20): "*The legal fixing of the requirements has in most cases nothing to do with the performance but no doubt results from the relationship of the position to the central values of the society or from the power held by the organized holders of this position*".

Tab. 5. Criteria for a professionalized career position

- Specialized and systemized knowledge
- Abilities based on theoretical knowledge
- Acquisition of abilities by training and practice
- Competence must be verified by an examination
- The profession is organized
  - scientific society or
  - professional organization
- Service ideal
- Validity of a special "code of ethics"
- Standard tariffs for payment

To obtain an overview of the international and European situation regarding the legal definition of the profession of clinical chemistry, the study "Education and Training for Clinical Chemistry" (21) carried out by the IFCC has been analysed (fig. 2). Worldwide in about 63% of the countries there is a direct legal definition of the profession by national laws. A more

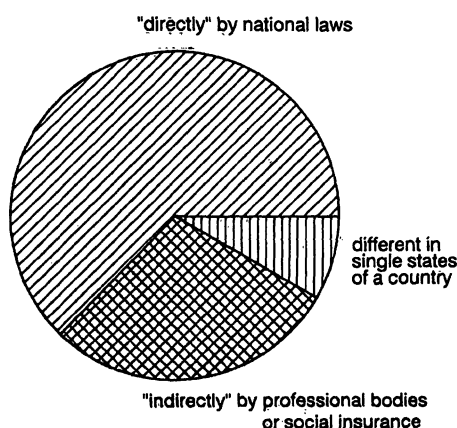


Fig. 2. Legal definition of the profession of clinical chemistry in 35 countries (Data from *M. Rubin & P. Lous* (21))

detailed analysis shows that these are predominantly those countries having a public health system. In contrast there are about 29% of the countries in which the demands are met "indirectly", i. e. through professional selfgoverning bodies or social insurance systems (22).

In Germany the situation is presently very complicated. In the Federal Republic there is no law governing the profession of the clinical chemist (23, 24) whereas clinical chemists in the German Democratic Republic are accredited by the government. In several European countries (Bulgaria, Czechoslovakia, Austria, Hungary) the position of a director of the hospital laboratory is reserved for physicians (25).

### Professional Qualification

One of the most important questions with regard to clinical chemistry is the professional qualification. This is the qualification which anybody wishing to be successfully active as clinical chemist must have.

This is not an easy question to answer because clinical chemistry is an interdisciplinary subject of considerable scope and in addition, as we have seen, various modes of thinking are used alongside other within the discipline. To take up an old proverb, a qualified profession requires training of mind, heart and hand, i. e. cognitive knowledge, an emotional attitude in line with the profession and finally also "skill", i. e. certain psychomotoric abilities (26).

To summarize the knowledge and abilities required by a clinical chemist figure 3 deals with the basic knowledge. It corresponds to individual subjects which are taught within the scope of a medical or scientific study. This basic knowledge forms the scientific background for clinical chemistry. In addition

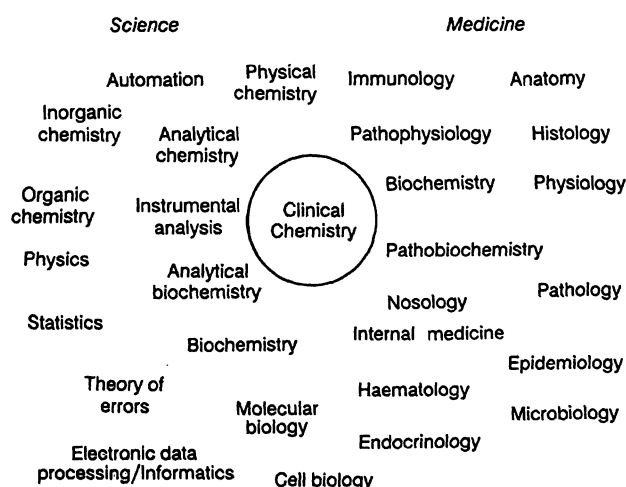


Fig. 3. Scientific background required for clinical chemistry

there is also a body of specialist knowledge to be acquired in clinical chemistry. This knowledge is exemplified in table 6. The essential knowledge in clinical medicine is very difficult to define. Such a definition requires a detailed subject catalogue, as submitted for example by the German Society of Clinical Chemistry (27). Finally, for the area of "centralized analytical activity" some further special knowledge is important, without which a hospital laboratory cannot be effectively managed (tab. 7) (28). It would be going too far to discuss here the qualifications for the field of research in clinical chemistry. With regard to pathobiochemical research, attention is drawn to the comments of *Trautschold* (29) and *Gerok* (30) at the Merck Symposium 1977, which are still valid today.

Tab. 6. Necessary special knowledge for conducting clinical chemistry

#### Analytical methodology

##### Examples:

optical methods  
substance separating methods  
e. g.: chromatography, ultracentrifugation  
mass spectrometry  
immunochemical methods  
molecular biological methods  
haematological methods (including coagulation)  
endocrinological methods  
special toxicological methods  
mechanization/automation

#### Use of clinical chemical tests in clinical medicine

##### for:

diagnostics, prognostics, preventive medicine, therapy control including therapeutic drug monitoring

#### Evaluation of clinical chemical tests

##### including:

interference factors and influence factors

Tab. 7. Special knowledge for "centralized analytical activity"

#### Management

Organization of the laboratory and its working flow

#### Use of electronic data processing

##### for:

work control, evaluation of findings, presentation of findings, performance statistics, accounting

#### Personnel management

#### Economic management

Finally, as for any other demanding professional position, certain "extrafunctional qualifications" (31) are desirable for a clinical chemist. Examples of this are the ability to enter into a dialogue with the clinician

and the ability and readiness to carry out interdisciplinary research in a team. Generally speaking, the clinical chemist should be able to look far beyond the borders of his own discipline.

### Recruiting Scientific Personnel for the Professional Field of Clinical Chemistry

Having outlined the professional qualification for clinical chemistry the question arises as to where suitably educated persons can be found to train for the profession of clinical chemist? This question will first be answered empirically, using the already mentioned international study of IFCC. Figure 4 shows which entry qualifications are usual at present. In 76% of the countries (European countries 57%) clinical chemists are recruited both from physicians and from scientists. The various subjects outside human medicine are classified again in figure 5. As can be seen, worldwide, biochemistry with 41% contributes a larger proportion than chemistry and pharmacy. In European countries, chemistry, biochemistry and pharmacy show the same proportion of about 29% each.

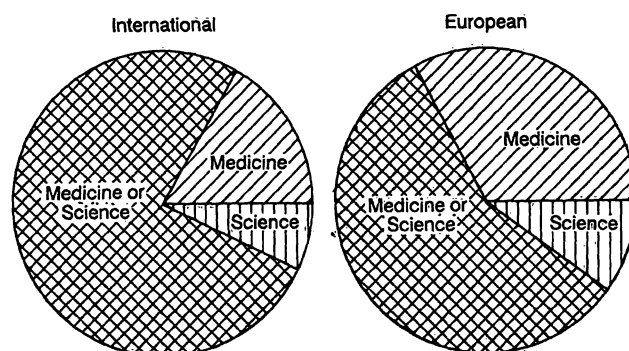


Fig. 4. Entry study for education in clinical chemistry (Data from *M. Rubin & P. Lous* (21)). Left side: international (42 countries), right side: European (21 countries)

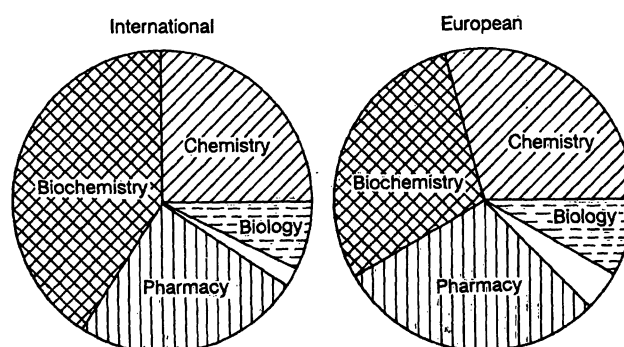


Fig. 5. Non-medical subjects as qualifications for entry to clinical chemistry (Data from *M. Rubin & P. Lous* (21)). Left side: international, right side: European. The unlabeled sector represents veterinary medicine

These empirical data reflect various influences. Firstly, the historical differences mentioned lead to preference of certain subjects in different countries, for example pharmacy in France. Secondly, with some exceptions it has become increasingly difficult to win physicians to the profession of the clinical chemist (32). It would appear that in a period of rapid advances in clinical medicine the subject of clinical chemistry is far down the popularity scale.

As seen from the detailed analysis of clinical chemistry as a scientific discipline and as a profession, the interdisciplinary aspect of the subject is a special feature. A necessary result of this is *the need to win over to clinical chemistry both persons with a medical training and persons with an education in science*. Only then will it be possible to cover the entire broad scope of this discipline. Apart from this discipline-oriented argument, professional and social arguments also show the need to open up access to the profession both to physicians and to scientists. Daheim puts it like this (33): *"The professional circle must decide whether they want to take in only members who have gone along the prescribed path or whether they also want to take in by way of exception qualified members of auxiliary and related professions as well. If this is not the intention then in future the profession will attract mainly individuals looking for a secure career and the 'enthusiasts' will stay away."*

### Acquiring the Necessary Qualification for the Subject of Clinical Chemistry

What is the best way of acquiring the necessary qualification for the profession of a clinical chemist? This question touches the very difficult problem of postgraduate training and requires careful consideration.

In the pioneering days of the discipline, it was considered expedient in Germany to acquire the necessary knowledge in a *double study*, for instance chemistry and medicine. In recent years, this approach has become increasingly problematic. Firstly, with the present lengths of courses the student finishes his examinations too late. If the rising generation does not enter the actual professional field until it is about 30 years old, the phase of creative activity in many cases will be too short for outstanding scientific achievements. Secondly, in spite of the double study, important parts of the necessary qualifications still had to be acquired later.

The alternative concept which has now established itself throughout the world is to impart specifically the qualification for the profession of a clinical chemist by postgraduate training or further education. *Postgraduate training* takes place in the form of spe-

cific courses lasting several years at universities. An example which can be mentioned is the American program (34) which was created at the start of the seventies under the pressure of a manpower crisis in clinical chemistry, and which mean-while has led to Ph. D.'s playing an outstanding part in American clinical chemistry. The concept of a *further training in the professional position* (German term "Weiterbildung"), which has been the usual one for medical specialists for a long time, was developed particularly in Europe. If this path of qualification is followed, the incoming clinical chemist acquires the necessary knowledge and abilities as an assistant in a clinical chemistry laboratory under the conditions and demands of daily routine work in a period of about 3 to 5 years; this knowledge and these abilities must then be tested in a concluding examination. This path has the advantage of being close to practice and if it is correctly devised permits the absolutely essential insight into clinical medicine. For postgraduate training, various international and national curricula exist. An IFCC-IUPAC recommendation of 1982 describes a two-year training course based on a university degree in chemistry, biochemistry, pharmacy or biomedical technology (35). Table 8 is intended to briefly compare the present training provisions in some European countries (taken from Breuer (36)).

Attention should also be drawn to a special aspect resulting from our analysis of clinical chemistry, which concerns the theory of science. The clinical chemist must learn to adopt two ways of thought, that of theoretical science and that of practical science. The Polish medicine theoretician *Ludwik Fleck* drew attention to the social dependence of thought (37). He coined the term, "thought style" ("Denkstil") which develops in a group of scientists (a "thought collective"). The thought style *"is characterized by common features in the problems of interest to a thought collective, by the judgement which the thought collective considers evident, and by the methods which it applies as a means of cognition"* (38). A research group, scientists of an institute or the scientific community of a discipline are examples of a thought collective which can develop a characteristic thought style. If these ideas are accepted, the clinical chemist just beginning would best be able to learn the way of thought in a suitable group of scientists with constant interchange of ideas. An example may help to explain this. The natural scientist who is used to thinking in natural laws and probabilities will learn from a constant exchange of ideas with the clinician that, in contrast to natural science, his findings are singular statements which relate only to a specific patient. He must learn to investigate whether the abstract concept of the disease is applicable to the individual case (39).

Tab. 8. Training of the clinical chemist in the countries of the European Community (taken from *Breuer* (36))

Country	Entry studies (years)	Postgraduate training	Remarks
Belgium	chemistry 4 pharmacology 5 medicine 7	5 years-1 year haematology 1 year microbiology 1 year clinical chemistry	
Federal Republic of Germany	medicine 6 biochemistry 6 chemistry 6	5 years-3-4 years in hospital laboratories	examination at the end of post-graduate training; no recognition by the government
Danmark	Akademiingeniør biochemistry Civilingeniør pharmacy medicine	5 years	only physicians can acquire the title of clinical chemist
German Democratic Republic	biology 5 biochemistry 5 chemistry 5 pharmacy 5	5 years in specialized laboratories	about 80% of the hospital laboratories are directed by "special chemists for medicine", about 20% by laboratory physicians
France	medicine 6 pharmacology 5	1. examination 2. 8 semester "concours de l'internat des hospitaux" in microbiology, haematology, clinical chemistry, parasitology 3. 1 semester in a hospital	4 examinations during postgraduate training; at the end of postgraduate training certification as clinical chemist = biologiste clinique
Greece	chemistry medicine pharmacology	4 years in biochemical laboratories	nearly all clinical chemists graduated in chemistry
United Kingdom	chemistry biochemistry (medicine)	5-8 years in an accredited laboratory	different examination depending on entry qualification
Netherlands	chemistry chem. technology pharmacy  biology	2 years clinical chemistry; 1-1.5 years haematology; 0.5-1 year special areas of clinical chemistry; at least 4 years in a hospital laboratory	examination in different areas of clinical chemistry; 1 year study in analytical biochemistry before postgraduate training in clinical chemistry
Ireland	biochemistry	4-5 years in a clinical chemical or clinical biochemical laboratory	
Italy	chemistry	clinical chemistry	only chemists are allowed to perform clinical chemical analyses. Analyses in other fields only by physicians
Luxembourg	chemistry pharmacology medicine	4 years	because many students from Luxembourg finish their studies in foreign countries, nearly all qualifying examinations are recognized
Portugal	biochemistry 4 biology chemistry chemical-engineering medicine veterinary medicine pharmacy	3 years practical work at a laboratory	a clinical laboratory can be directed only after graduation in medicine or pharmacy
Spain	chemistry 5 medicine 6 pharmacy 5 biology 5	4 years in a clinical chemical laboratory; examination in all of the 4 entry subjects; examinations yearly during postgraduate training	



## The Change of the Professional Field of Clinical Chemistry in the Future

Like broad areas of the biosciences and of medicine, the discipline of clinical chemistry is undergoing an extremely rapid change at present. There are several reasons for this.

The predominant factor here is the explosive *growth of knowledge* due mainly to the successes of molecular biology, immunology, and cell biology. This growth of knowledge will also influence and change clinical chemistry. The classical methods of clinical chemical investigations, which were restricted predominantly to the body fluids and the extracellular compartment, will be replaced by new investigation techniques. The new possibilities will bring about rapid advances in the research of the pathogenesis of diseases.

A second factor is directly related to this. The rapid increase in knowledge leads to a *flood of information* which must be controlled with suitable methods. We shall have to wait and see whether the artificial intelligence of computers and expert systems will be suitable and adequate to do this.

A third factor governing the change in clinical chemistry resides in the still increasing mechanization and automation of methods. Modern instruments developed by industry are, however, hardly transparent to the user. The effects of an error for instance in an apparatus component on the whole analytical system can no longer be assessed. The clinical chemist runs the risk of losing the control over his instruments. The philosophy of technology describes this under the concept of "*technocracy*" (40): With the advance of technical development the actions of man finally become dependent only on technical factors, "material constraints". Man loses the possibility of taking a free decision on the use of the machine. When using his machines, the clinical chemist is also threatened by technocracy. The aim here must be to recover the freedom of decision by self-expertise.

A fourth factor which will influence clinical chemistry in the future is the *economic situation* of the health system in many countries. The struggle for the distribution of the resources in the health system is already in full swing. In this context, it is important for clinical chemistry that in many countries a not inconsiderable part of a physician's fees comes from clinical chemical investigations.

The aforementioned influences are a great challenge to the clinical chemist in the next decade. We shall be able to meet this challenge only if clinical chemistry is further developed as an interdisciplinary subject, if it is opened up fully to physicians and scientists, and if it willingly accepts teamwork with the clinical disciplines. These changes will require continuous adaptation of the knowledge which the clinical chemist must acquire. This is where universities and scientific specialist societies are expected to update curricula for postgraduate studies and further training and above all to offer effective training facilities.

## Clinical Chemistry in the European Community

The political development within the European Community means that clinical chemists will work more closely together than in the past when they were separated by borders. The differences in the professional field of clinical chemistry may prove a hindrance here. On the other hand, as this analysis has shown, this variety is an expression of the interdisciplinary nature which must be preserved if the discipline is to be able to meet the challenge of our future. It is therefore a matter of urgency for the professionals that clinical chemists of the countries of the European Community jointly define the framework for the clinical chemist in the European Community (see also the editorial in this Journal (41)). A concept of the professional field supported by all those involved opens up the possibility of recognition by the European Commission. This is the only way of avoiding one-sided regulations that are inadequate and inappropriate to the nature of the discipline.

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22. The Education Committee of the IFCC and the Commission on Teaching in Clinical Chemistry of the IUPAC published definitions of the terms "certification", "licensure" und "accreditation":  
Cediel, N. de, Fraser, C. G., Deom, A., Josefsson, L., Worth, H. G. J. & Zinder, O. (1989) Guidelines (1988) for training in clinical laboratory management. *J. Clin. Chem. Clin. Biochem.* 27, 393–401.
23. In accordance with the Federal Medical Code, medical treatment ("Heilbehandlung") can be performed only by a physician. Special laws of the Federal States ("Kammergesetze") place the detailed supervision of the medical profession in the hands of the medical boards ("Ärztelkammern"). For example, they regulate the demands made of a physician for laboratory medicine, such a physician carrying out among other things clinical chemistry. The scope of activities within the state social insurance system is defined by a *State Insurance Code* ("Reichsversicherungsordnung") and the rules of the associations of physicians working within this system ("Kassenärztliche Vereinigungen"). These concern for example clinical chemical examinations which are carried out by registered physicians. A special professional law governs medical technologists, the same law also covering the activities of natural scientists in the area of clinical chemistry.
24. Stamm, D. (1990) Zur Tätigkeit eines Arztes für Laboratoriumsmedizin. *Deutsche Gesellschaft für Klinische Chemie — Mitteilungen*, 21, 109–117.
25. I. c. (7).
26. The goals for the education of clinical chemists are defined in the following Guidelines of IFCC and IUPAC:  
Fraser, C. G., Cediel, N. de, Deom, A., Josefsson, L., Worth, H. G. J. & Zinder, O. (1989) Guidelines (1986) for the preparation of aims and objectives for the teaching of clinical chemistry. *J. Clin. Chem. Clin. Biochem.* 26, 163–167.
27. New version of the syllabus for the final examination in clinical chemistry:  
Neufassung des Gegenstandskataloges für die Abschlußprüfung zur Erteilung der Anerkennung als Klinischer Chemiker vom 1. Juli 1986. Deutsche Gesellschaft für Klinische Chemie — Mitteilungen 17, 100–103 (1986).
28. See: I. c. (22).
29. Trautschold, I. (1978) Aufgaben, Möglichkeiten und Grenzen der Klinischen Biochemie in der Erforschung pathologischer Zustände und Mechanismen aus der Sicht des Klinischen Chemikers. In: Lang, H., Rick, W. & Róka, L. (Hrsg.) *Aktuelle Probleme der Pathobiochemie*. Merck-Symposium 1977, Springer-Verlag, Berlin-Heidelberg, New York, pp. 87–99.
30. Gerok, W. (1978) Aufgaben, Möglichkeiten und Grenzen der Klinischen Biochemie in der Erforschung pathologischer Zustände und Mechanismen aus der Sicht des Klinikerns. In: Lang, H., Rick, W. & Róka, L. (Hrsg.) *Aktuelle Probleme der Pathobiochemie*. Merck-Symposium 1977, Springer-Verlag, Berlin, Heidelberg, New York, pp. 100–109.
31. Ralf Dahrendorf used this term to describe special abilities which are needed at working places in the developed mechanized industry:  
Dahrendorf, R. (1956) Industrielle Fertigkeiten und soziale Schichtung. *Kölner Zeitschrift für Soziologie und Sozialpsychologie* 8, 540–568 (see page 553 f.).
32. Purdy, W. & Melville, R. S. (1970) The manpower crisis in clinical chemistry. *Anal. Chem.* 42, 32A–38A.
33. o. c. (19), p. 57 (translated from German).
34. I. c. (32).
35. Porter, C. J. & Curnow, D. H. (1983) A scheme for a two year postgraduate course in clinical chemistry. *J. Clin. Chem. Clin. Biochem.* 21, 185–191.
36. Breuer, J. (1990) Harmonisierung der Ausbildung zum Klinischen Chemiker in den Ländern der Europäischen Gemeinschaft. *Deutsche Gesellschaft für Klinische Chemie — Mitteilungen* 21, 65–67.
37. (a) Ludwik Fleck (1935) *Entstehung und Entwicklung einer wissenschaftlichen Tatsache*. B. Schwabe, Basel.  
(b) Reprint: Suhrkamp Taschenbuch Wissenschaft 312, Frankfurt 1980.  
(c) English edition: Ludwik Fleck (1979) *Genesis and Development of a Scientific Fact*. (Trenn, T. J. & Merton, R. K., eds.) The University of Chicago Press, Chicago and London.
38. o. c. (37c), p. 99.
39. I. c. (30).
40. Schelsky, H. (1961) *Der Mensch in der wissenschaftlichen Zivilisation*. Köln, Opladen.
41. Brombacher, P. J., Breuer, J. & Sanders, G. T. B. (1990) Clinical Chemistry in the European Community. Development of international regulations on education, recognition and free change of professionals (Editorial). *J. Clin. Chem. Clin. Biochem.* 28, 189–191.

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